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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,773	02/05/2004	Timothy F. Kowalik	UMY-079	8486

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,773

Applicant(s)

KOWALIK, TIMOTHY F.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-44 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 27-30, 38-44, drawn to compositions and methods comprising an siRNA, classifiable in class 536, subclass 24.5.
- II. Claims 8-18, drawn to methods of inhibiting the expression of more than one protein with a single agent, classifiable in class 435, subclass 6 and class 514, subclass 44.
- III. Claims 19-26, 31-38, drawn to nucleic acid compositions and host cells, classifiable in class 536, subclass 23.1.

Applicants are also required to elect a single target nucleic acid, nucleic acid construct, and/or corresponding SEQ ID NO. with the corresponding elected Group from claims 2-4, 11, 13, 17, 18, 19, 23, 28 or 31.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to chemically, biologically, structurally and

functionally distinct compounds. The siRNA of Group I are chemically and structurally distinct from the inhibitory molecules of Group II, and from the nucleic acids of Group III. The searches required for proper examination of each distinct group are not coextensive: A search of the nucleic acids of Group I would not be coextensive with the search required for the proper examination of Groups II or III, although the searches may be overlapping.

The different inventions drawn to each polynucleotide, target sequence and corresponding SEQ ID NO. are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different polynucleotides are chemically, biologically, structurally and functionally different and distinct from each other. The methods involving the use of a distinct polynucleotide utilize a different and distinct composition, and so utilize distinct methods steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Furthermore, searching the inventions of Groups comprising all of these different oligonucleotide molecules, and the methods comprising them together would impose a serious search burden. In the instant case, the search of the distinct methods and compositions are not coextensive. There is a search burden also in the non-patent literature. Prior to the concomitant construction and utilization of the different nucleic acid constructs of interest there may be journal articles devoted solely to one Group that would not have described the compositions and methods of the other Group.

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Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of the different Groups together.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the compounds and methods comprising administration of different nucleic acid molecules are unrelated as they comprise distinct steps and utilize different nucleic acid constructs which demonstrates that each method has a different mode of operation. The methodology and materials necessary for each of these distinct methods differ significantly, and each Group constitutes a biologically, chemically and functionally distinct and different composition and method and therefore each involves a patentably distinct invention. Therefore, each method is divergent in materials and steps. For these reasons the inventions of these different Groups are patentably distinct.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different molecules, and their corresponding SEQ ID Nos. listed in claims 2-4, 11, 13, 17, 18, 19, 23, 28 or 31, and encompassed by claims 1-44, are subject to restriction. In the instant case, one independent and distinct polynucleotide sequence will be examined in a single application without restriction. Those sequences which are patentably indistinct from the sequence selected by the applicant will also be examined.

Claims 1-44 specifically embrace different polynucleotides with different SEQ ID Nos. or targeting different target nucleic acid sequences. Each of these molecules is considered to be structurally independent, because each is represented by a unique

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nucleotide sequence. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark Office to search and examine. In view of the foregoing, applicants are required to elect up to 1 (ONE) polynucleotide or nucleic acid construct (SEQ ID No.).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
9-28-06

J. Zara
TC 1600
JANE ZARA, PH.D.
PRIMARY EXAMINER